

1 statements about Merck's promotion of Vioxx.

2 [T]he Division of Drug Marketing, Advertising, and Communications
3 (DDMAC) has reviewed your promotional activities and materials and has
4 concluded that they are false, lacking in fair balance, or otherwise misleading
5 in violation of the Federal Food, Drug, and Cosmetic Act.

6

7 You assert that Vioxx does not increase the risk of MIs and that the VIGOR
8 finding is consistent with naproxen's ability to block platelet aggregation like
9 aspirin. That is a possible explanation, but you fail to disclose that your
10 explanation is hypothetical, has not been demonstrated by substantial evidence,
11 and that there is another reasonable explanation, that Vioxx may have pro-
12 thrombotic properties.

13

14 Your minimizing these potential risks and misrepresenting the safety profile
15 for Vioxx raise significant public health and safety concerns. Your
16 misrepresentation of the safety profile for Vioxx is particularly troublesome
17 because we have previously, in an untitled letter, objected to promotional
18 materials for Vioxx that also misrepresented Vioxx's safety profile.

19

20 The promotional audio conferences identified above, arranged by, and
21 presented on behalf of, Merck were false or misleading in that they minimized
22 the MI results of the VIGOR study, minimized the Vioxx/Coumadin drug
23 interaction, omitted important risk information, made unsubstantiated
24 superiority claims, and promoted Vioxx for unapproved uses and an
25 unapproved dosing regimen.

26

27 Your suggestion that COX-2 inhibitors, including Vioxx, have an overall
28 safety profile that is superior to other NSAIDs is misleading because such an
29 advantage has not been demonstrated. In fact, in the VIGOR study the
30 incidence of serious adverse events was **higher** in the Vioxx treatment group
31 than in the naproxen treatment group

32

33 Your audio conferences are misleading because they promote Vioxx for
34 unapproved uses Your claim is misleading because it suggests that Vioxx
35 is effective for the treatment of rheumatoid arthritis when this has not been
36 demonstrated.

37

38 Your promotional audio conferences are also misleading because they suggest
39 that Vioxx is safe and effective for other unapproved uses such as the
40 prevention of cancer and invasive cancer, and for the treatment of Alzheimer's
41 disease and gout.

1
2 The promotional activities and materials described above minimize the
3 potentially serious cardiovascular findings that were observed in the VIGOR
4 study, minimize the Vioxx/Coumadin drug interaction, omit crucial risk
information associated with Vioxx therapy, contain unsubstantiated
comparative claims, and promote unapproved uses.

5 (COX-2 Notebook 2, Tab 58.)

6 37. Neither the adverse journal and newspaper articles nor the FDA criticisms did
7 anything to hinder Merck's aggressive marketing of Vioxx. In the Fall of 2001, Merck
8 launched Project Offense to increase Vioxx market share, focusing on efficacy to divert
9 attention from the safety concerns. Project Offense included instructions to field sales staff
10 on how to address physician safety concerns, advising them again to review the entire CV
11 Card with doctors, and point out to them Merck's data which purported to show that Vioxx
12 was actually safer than other NSAIDs.

13 **Merck Resisted Changes Recommended by the FDA to**
14 **Warn about Heart Attack Risks in Vioxx Labeling**

15 38. After the VIGOR study, the FDA recommended that the label for Vioxx be
16 changed to add a warning which included a statement that: "The risk of developing
17 myocardial infarction in the VIGOR study was five fold higher in patients treated with Vioxx
18 50 mg (0.5%) as compared to patients treated with naproxen (0.1%)" Merck objected
19 to the change recommended by the FDA.

20 39. On February 15, 2002, the FDA recommended that the Vioxx label include a
21 Kaplan-Meier curve to graphically show a worsening of cardiovascular risks as the length
22 of exposure to Vioxx increased. Merck again objected.

23 40. In addition to the misleading CV Card, Merck developed a number of other
24 materials designed to misrepresent the safety and efficacy of Vioxx. It produced a videotape
25 to train its salespeople to view doctors' concerns about Vioxx's heart risks as "'obstacles" to
26 be avoided or dismissed.

27 41. Merck produced a training document titled "Dodge Ball Vioxx," consisting of
28 12 pages of statements or questions a salesperson might receive from a doctor about the

1 cardiovascular safety of Vioxx. The last 4 pages of the document contain the single word
2 "DODGE!" in capital letters.

3 **Merck Attempted to Suppress and Refute Research Showing That**
4 **Vioxx Increases the Risk of Heart Attacks**

5 42. Two months after Vioxx went on the market in 1999, Nancy Santanello, head
6 of Merck's epidemiology department, wrote an e-mail about "physicians to neutralize:" Her
7 email states: "Attached is the complete list of 36 physicians to neutralize with background
8 information and recommended tactics. You will notice that some have already been
9 'neutralized'." That e-mail also identified a previous e-mail which had a subset of the 36
10 physicians "we would like to get involved in Merck clinical research" and that the e-mail's
11 recipient should "be aware of our most challenging (and also most vocal) national and
12 regional physicians."

13 43. During 1999, Merck paid Dr. Gurkupal Singh of Stanford University Medical
14 School up to \$2,500 for giving talks to other doctors supporting the use of Vioxx. Dr. Singh
15 gave 40 talks over 7 months. Dr. Singh became concerned about the cardiovascular risks of
16 Vioxx after the VIGOR study was completed. Dr. Singh repeatedly asked Merck for the
17 VIGOR data so he could analyze them for himself. When Dr. Singh persisted in his requests,
18 Merck warned him that there would be serious consequences if he didn't stop. In 2000, Dr.
19 Singh began to publicly express his concern about the cardiovascular risks of Vioxx.

20 44. A dossier of Dr. Singh's activities regarding Vioxx was prepared for Merck
21 senior vice president, Dr. Louis Sherwood. On October 28, 2000, Dr. Sherwood called Dr.
22 Singh's boss, Stanford Medical School professor Dr. James Fries, and hinted that there would
23 be repercussions for Stanford if Dr. Singh continued making public statements about the
24 cardiovascular risks of Vioxx.

25 45. In January 2001, Dr. Fries wrote to former Merck CEO, Ray Gilmartin,
26 complaining that Dr. Sherwood had called him to try to get him to make Dr. Singh stop
27 saying negative things about Vioxx in lectures. Sherwood warned that if Dr. Singh didn't
28 stop bashing Vioxx, he would "flame out" and "there would be consequences for [Dr.

1 Sherwood] and Stanford."

2 46. Merck sponsored a study of Vioxx by several doctors, including Dr. Daniel
3 Solomon and Dr. Jerry Avorn. Merck scientists helped develop the study protocol and signed
4 off on all aspects of the study design. However, when the study showed an increased risk of
5 heart attacks with Vioxx, Merck required one of the study's coauthors, who was an employee
6 of Merck, to remove her name from the study. Although it funded the study and approved
7 its design, Merck publicly discredited the study in May 2003, claiming that there were
8 "serious limitations to the analysis."

9 **Merck Deleted Data About Heart Attacks From an Article in**
10 ***The New England Journal of Medicine*, Causing the Article to be**
Incomplete and Deceptive

11 47. In November 2000, an article reporting on the VIGOR study, an important
12 clinical trial of Vioxx, was published in *The New England Journal of Medicine*. *The New*
13 *England Journal* is one of the world's most prestigious and influential medical journals. The
14 VIGOR study was financed by Merck and produced information about heart attacks suffered
15 by study participants who took Vioxx and by those who took naproxen instead of Vioxx.
16 Throughout its marketing campaign for Vioxx, Merck relied on the VIGOR article in *The*
17 *New England Journal* to support its claim that Vioxx was safe.

18 48. The VIGOR study showed that 20 of the participants taking Vioxx had heart
19 attacks compared to only 4 of the participants taking naproxen. Although at least 2 of the 3
20 lead authors of the article that appeared in *The New England Journal* knew several months
21 before the article was published that there were 20 heart attacks among the participants
22 taking Vioxx, the article reported that 17, not 20, of the Vioxx participants had heart attacks.

23 49. Electronic records show that two days before the article was submitted to *The*
24 *New England Journal* for publication, a Merck editor deleted information about 3 of the heart
25 attacks in the Vioxx participants. The data deleted by Merck made Vioxx appear less risky
26 in the article than the VIGOR trial actually proved that it was. Merck knew that, by deleting
27 data about heart attacks, the article would present an incomplete, inaccurate, and deceptive
28 picture of the true risk of taking Vioxx.

1 50. The editors of *The New England Journal* have publicly stated that the
2 information deleted by Merck calls into question "the integrity of the data" appearing in the
3 article, and have called for the article's authors to submit a correction.

4 **Merck Pressured Doctors to Prescribe Vioxx,
5 and Urged Patients to Ask For It, Even Though it Was Far More
6 Dangerous and Expensive than Other Equally Effective Drugs**

7 51. Studies by the Mayo Clinic, the Veterans Affairs Department, and the Kaiser
8 Permanente organization showed that Vioxx is no more effective in relieving pain than other
9 NSAIDs such as aspirin, ibuprofen, and naproxen which can be purchased without a
10 prescription at a fraction of the cost of Vioxx.

11 52. Only a small percentage of people who took Vioxx were at high risk of
12 stomach bleeding if they took NSAIDs that blocked COX-1 and COX-2. However, Merck
13 promoted Vioxx to doctors and patients as a drug of first choice in treating pain. Thus,
14 although the majority of people who took Vioxx did not need, or benefit from, Vioxx's
15 reduced effect on the stomach, all people who took Vioxx were exposed to a five-fold
16 increase in the risk of heart attacks.

17 53. All Vioxx sold in Montana cost many times more than generic aspirin,
18 ibuprofen, and naproxen. Furthermore, a combination of a generic NSAID, such as
19 ibuprofen or naproxen, with a drug that protects the stomach, such as Prilosec, is almost as
20 safe for the stomach as Vioxx, with no increased heart attack risk.

21 **Merck Aggressively Marketed Vioxx to the Public and to Doctors**

22 54. Despite knowing before and after FDA approval that Vioxx caused increased
23 cardiovascular risk, Merck has aggressively marketed Vioxx from the beginning.

24 55. When Merck launched its marketing campaign for Vioxx in 1999, it hired 700
25 new salespeople to market the drug to doctors and eventually assigned over 3,000 salespeople
26 to promote Vioxx in face-to-face discussions with doctors.

27 56. Merck put its salespeople through intensive training exercises to persuade
28 doctors to prescribe Vioxx and provided numerous incentives to Merck salespeople for
increasing the share of Vioxx that any doctor prescribed.

1 57. Salespeople were instructed to use the systems and techniques it had taught
2 them to convince doctors that Vioxx was a safe and effective pain reliever. On information
3 and belief, it is alleged that Merck salespeople used some or all of the required sales tactics
4 to induce Montana doctors to prescribe Vioxx to Montana citizens.

5 58. On October 3, 2001, Merck launched a direct-to-consumer advertising
6 campaign for Vioxx with television ads featuring Olympic skater Dorothy Hamill. These ads
7 ran repeatedly in Montana. The ads failed to warn consumers that Vioxx increased the risk
8 of cardiovascular problems.

9 59. Merck's Vioxx advertising and marketing campaign as a whole sought to create
10 the image, impression, and belief that Vioxx was safe for adults and had fewer side-effects
11 and adverse reactions than other pain relief medications. Merck had no reasonable grounds
12 to believe that these representations were true. Merck purposefully misrepresented,
13 understated, and otherwise downplayed the serious health hazards and risks associated with
14 Vioxx.

15 60. Merck's false and misleading promotion induced the State of Montana,
16 Montana corporations, and Montana citizens to purchase Vioxx in many instances where it
17 provided no benefit over other less risky and less expensive drugs.

18 61. Merck's false and misleading promotion persuaded Montana doctors to
19 prescribe Vioxx in many instances where they would not have done so if Merck had provided
20 them with complete and accurate information it knew about the efficacy and cardiovascular
21 risks of Vioxx.

22 62. Merck's misleading and false advertisements, promotional materials, and
23 public statements were extremely successful in building the market for Vioxx. It contributed
24 to Vioxx reaching \$2 billion in sales faster than any drug in Merck's history. Vioxx sales in
25 2003 alone were \$2.5 billion.

26 63. Merck estimates that there were 105 million U.S. prescriptions written for
27 Vioxx from May 1999 through August 2004. Based on this, Merck estimates that 20 million
28 people have taken Vioxx in the United States since 1999.

COUNT I**The Montana Food, Drug, and Cosmetic Act:
False and Misleading Advertising**

64. Since 1947, the sale of drugs within Montana has been regulated by the Montana Food, Drug, and Cosmetic Act (Montana FDCA), Mont. Code Ann. §50-31-101, et seq.

65. The Montana FDCA prohibits false or misleading advertising of drugs within the State. Mont. Code Ann. §50-31-501(1,5). A drug advertisement is "deemed to be false if it is false or misleading in any particular." Mont. Code Ann. §50-31-107(1). A drug advertisement is also deemed to be misleading if it fails to reveal material facts about the consequences which may result from using the drug in the manner in which the advertisement suggests that it be used. Mont. Code Ann. §50-31-107(2).

66. The Montana Legislature has charged the Attorney General with the duty to bring appropriate proceedings in court to remedy violations of the Montana FDCA. Mont. Code Ann. §50-31-505.

67. In violation of the Montana FDCA, Merck's advertisements made false and misleading claims to doctors and the public in Montana about the effectiveness of Vioxx.

68. As a result of Merck's violation of the Montana FDCA, the State and its citizens, corporations, and other business entities have been damaged and are entitled to all the remedies and damages provided by law.

COUNT II**Deceit**

69. Plaintiff repeats and realleges the paragraphs above as if set forth fully herein.

70. In Merck's advertising and promotional materials, in its marketing tactics in face-to-face meetings with doctors, in its press releases, and in its public advertisements, Merck made suggestions of fact that Merck knew were not true. Such conduct constitutes deceit under Mont. Code Ann. §27-1-712.

71. Merck, in its face-to-face meetings with doctors, in its press releases, and in

1 public advertisements, suppressed facts about the cardiovascular dangers of Vioxx such that
2 Montana doctors and the public were misled about its dangers. Such conduct constitutes
3 deceit under Mont. Code Ann. §27-1-712.

4 72. As a result of Merck's violation of Mont. Code Ann. §27-1-712, the State and
5 its citizens, corporations, and other business entities have been damaged and are entitled to
6 all the remedies and damages provided by law.

7 **COUNT III**

8 **Unfair Trade Practices and Consumer Protection Act Claim**

9 73. Plaintiff repeats and realleges the paragraphs above as if set forth fully herein.

10 74. In the course of business, Merck misrepresented and/or omitted material facts
11 about the safety and effectiveness of Vioxx. Merck misleadingly claimed that Vioxx was
12 safe and was as, or more, effective than traditional NSAIDs in treating chronic pain, that it
13 did not cause or contribute to any cardiovascular problem greater than any other NSAIDs,
14 and that Vioxx use should not be limited to patients with gastrointestinal problems who could
15 not use other NSAIDs.

16 75. Merck systematically suppressed and concealed material information it
17 developed or otherwise knew about the adverse cardiovascular effects of Vioxx and engaged
18 in a mis-information and dis-information campaign to conceal the truth.

19 76. Merck systematically sought to discredit or cast doubt upon scientific studies
20 and reports and the work of scientists which concluded that Vioxx caused or contributed to
21 adverse cardiovascular effects.

22 77. Merck systematically engaged in a false and misleading marketing and
23 advertising campaign to over-promote the use of Vioxx.

24 78. Merck's conduct, as described above, constitutes unfair and deceptive practices
25 in violation of Mont. Code Ann. § 30-14-103.

26 79. As consequence of Merck's violation of Mont. Code Ann. §30-14-103, the
27 State, its citizens, corporations, and business entities have been injured and suffered damages
28 and are, therefore, entitled to all the damages and remedies provided by law.

COUNT IV

Unjust Enrichment and Restitution

80. Plaintiff repeats and realleges the paragraphs above as if set forth fully herein.

81. Merck engaged in a systematic campaign to over-promote the use of Vioxx, claiming it was safe from any adverse cardiovascular effects and was as, or more, effective than traditional, significantly less expensive NSAIDs for treating pain and inflammation.

82. Merck knew that Vioxx causes or contributes to cardiovascular disease and myocardial infarction in users and is no more effective than much cheaper and safer non-steriodal, anti-inflammatory drugs.

83. Merck had a duty to the State Montana and to the citizens, corporations, and business entities of the State to disclose all material facts about its products and to refrain from over-promoting or falsely promoting its products as safe and more effective than traditional non-steriodal, anti-inflammatory drugs when it knew that was not true.

84. As a result of Merck's breach of this duty and the misleading suppression of the truth about Vioxx, Merck has sold millions of dollars of unnecessary and over-priced Vioxx to the State of Montana and its citizens, which likely caused adverse cardiovascular effects to the citizens of the State of Montana.

85. Merck has been unjustly enriched by its false, deceitful, and misleading conduct to the extent that the citizens of the State of Montana and the State of Montana have unknowingly paid excessive costs for Vioxx when they could have purchased significantly less expensive traditional pharmaceuticals that would have been equally effective and without the severe cardiovascular risks of Vioxx.

86. As a result of Merck's conduct, the State of Montana and its citizens have suffered substantial economic damages and are entitled to damages and all other available remedies.

WHEREFORE, the State of Montana, by and through Attorney General Mike McGrath, prays as follows:

1. That the Court adjudge and decree that Merck has engaged in the conduct

1 alleged herein.

2 2. That the Court adjudge and decree that Merck's advertising and promotion of
3 Vioxx was false and misleading in violation of the Montana FDCA.

4 3. That the Court adjudge and decree that Merck violated Mont. Code Ann. §27-
5 1-712 and that the State of Montana and its citizens were damaged thereby.

6 4. That the Court adjudge and degree that such conduct is unlawful and in
7 violation of Mont. Code Ann. § 30-14-103.

8 5. That the Court, pursuant to Mont. Code Ann. § 30-14-142, assess civil
9 penalties of \$10,000.00 against Merck for each violation of Mont. Code Ann. § 30-14-103
10 complained of herein.

11 6. That the Court, pursuant to Mont. Code Ann. § 30-14-131, enter an order
12 restoring to the State and to the citizens of the State all monies acquired by Merck by means
13 of its unlawful practices.

14 7. That the Court order Merck to pay restitution which would restore the State of
15 Montana and the citizens of the State of Montana the financial position that they would have
16 enjoyed absent Merck's false representations and over-promotion of Vioxx.

17 8. That the Court order Merck to disgorge all unjust profits from the sale of Vioxx
18 to the citizens of the State of Montana and the State of Montana.

19 9. That the Court award the State of Montana its attorneys fees and costs.

20 10. That the Court order such other and further relief as the Court deems just,
21 necessary, and appropriate.

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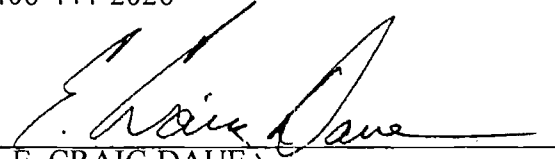
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1 Dated this 23^d day of December, 2005.

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DEMAND FOR JURY TRIAL

Plaintiff demands trial by jury of all issues of fact in this case.

Dated this 23rd day of December, 2005.

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Exhibit E

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT AT ANCHORAGE

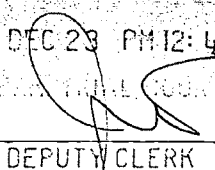
STATE OF ALASKA,)
)
 Plaintiff,)
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 vs.)
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 MERCK & CO., INC.,)
)
 Defendant.)

Case No: 3AN-05-14 292 ci

COMPLAINT

(AS 45.50.471, AS 45.50.501, AS 45.50.551)

The State of Alaska, Plaintiff herein, by and through its counsel, brings this Complaint against Merck & Co., Inc. ("Defendant") pursuant to the Unfair Trade Practices and Consumer Protection Act, AS 45.50.471 *et seq.*

STATE OF ALASKA
CLERK OF COURT
65 DEC 23 PM 12:42
BY  DEPUTY CLERK

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DEFENDANT

1. Defendant is an American pharmaceutical company incorporated under the laws and statutes of the State of New Jersey. Defendant can be served with process by serving its registered agent, CT Corporation System, 801 W. 10th Street, Suite 300, Juneau, Alaska 99801.

JURISDICTION AND VENUE

2. At all times material to this civil action, Defendant transacted business in Alaska by, among other things, advertising, soliciting, selling, and distributing the pharmaceutical product known as Vioxx to purchasers in Alaska. Therefore, this court has personal jurisdiction over Defendant.

3. This court has subject-matter jurisdiction based upon AS 45.50.501 and 45.50.551, which provide remedies to redress Defendant's conduct and authorize the State of Alaska to bring this action.

4. Because the State of Alaska is not a citizen for purposes of diversity jurisdiction, no federal court can exercise subject-matter jurisdiction over this case by virtue of diversity of citizenship. *State of Alaska v. K&L Distributors, Inc.*, 318 F.2d 498, 498 (9th Cir. 1963); *Tex. Dept. of Hous. & Cmty. Affairs v. Verex Assurance, Inc.*, 68 F.3d 922, 926 (5th Cir. 1995).

5. Venue is proper in this judicial district pursuant to Section 45.50.501 of the Alaska Statutes and Rule 3 of the Alaska Rules of Civil Procedure because some of

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Defendant's unlawful acts and practices that give rise to this Complaint arose in this judicial district and the Defendant is doing business in this judicial district.

DEFENDANT'S CONDUCT

6. All practices, acts, and omissions alleged herein to have been committed by Defendant were committed by Defendant's officers, directors, employees, or agents, who, at all times, acted on behalf of Defendant and whose practices, acts, and omissions were authorized and/or ratified by Defendant. Accordingly, Defendant is liable under the doctrines of vice-principal, respondeat superior and agency as those terms are defined and applied under the laws and statutes of Alaska.

7. Defendant began marketing Vioxx (generic name Rofecoxib) in May 1999, following a short clinical trial period. Vioxx was initially approved for osteoarthritis, the management of acute pain in adults, and the treatment of primary dysmenorrhea. Furthermore, in requesting that Vioxx be placed on the Alaska Medicaid Program's list of drugs subject to reimbursement, the Defendant represented that Vioxx was at least as safe as other drugs of a similar class and/or type used for the same purposes. Ultimately, Defendant withdrew Vioxx from the market on September 30, 2004, because it was unsafe. Research and clinical experience has revealed that Vioxx significantly increases the risk of heart attack and other serious cardiovascular and cerebrovascular medical complications.

8. From the time Defendant started developing Vioxx, through the date of its withdrawal from the market on September 30, 2004, Defendant engaged in knowing

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misrepresentations, including, but not limited to, direct representations to the Alaska Medicaid Program that Vioxx was safe and effective and advertising and promotional campaigns to Alaskans that falsely represented the safety of Vioxx. The Defendant misrepresented and suppressed evidence concerning the significant health hazards of Vioxx.

9. Defendant was aware that Vioxx caused serious and significant health hazards even before Defendant promoted Vioxx to physicians and to the State of Alaska and provided Vioxx to Alaskans. Defendant knew that cerebrovascular and cardiovascular problems occurred more frequently in patients receiving Vioxx than in patients receiving placebos or other medicines. Defendant's internal memos and e-mails, dating back to at least 1996, show that Defendant knew "how" and "why" Vioxx would cause significantly higher rates of cardiovascular problems in patients taking Vioxx, as compared to a control group.

10. Before Defendant began marketing Vioxx to the public in May 1999, Defendant knew clinical research, including its own, showed that Vioxx increased the risk of heart attack and adverse cardiovascular and cerebrovascular problems. However, Defendant did not disclose this prior knowledge, nor the additional knowledge Defendant obtained after it started successfully selling Vioxx to the public. Instead, the Defendant misrepresented and mischaracterized the data and information concerning Vioxx. Moreover, the Defendant launched an expensive, promotional advertising campaign to convince lay people to request Vioxx from their healthcare professionals for the treatment of their pain, and to promote, as safe, the use of Vioxx, even though the Defendant's own medical research confirmed its harmful effects. The Defendant also launched an aggressive campaign of intimidation against

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researchers and physicians who questioned the safety of Vioxx. The Defendant's deceptive and misleading representations were later recognized by the FDA in a letter to the Defendant wherein the FDA labeled the Defendant's promotional sales marketing and materials as "lacking in pure balance," "false," and "misleading." In recent months, investigators have learned that the Defendant deliberately removed data of some adverse cardiovascular and cerebrovascular events from data supplied to those outside the company.

11. It was not until September 30, 2004, that the Defendant finally admitted that Vioxx was not safe and posed such an unreasonable risk of harm to the public that it should be withdrawn from the market.

VIOLATIONS OF THE UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION ACT

12. Defendant's acts and practices were unlawful as that term is described in AS 45.50.471(a) in that Defendant used unfair methods of competition and unfair or deceptive acts or practices in the conduct of trade or commerce.

13. Defendant represented to the State, to physicians in Alaska, and to the public in Alaska that Vioxx had characteristics, uses, and benefits that it did not have. AS 45.50.471(b)(4).

14. Defendant advertised Vioxx with an intent not to sell it as advertised. AS 45.50.471(b)(8).

15. Defendant engaged in conduct creating a likelihood of confusion or of misunderstanding and which misled, deceived, or damaged buyers of Vioxx, including the

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State of Alaska, healthcare providers in Alaska, and Alaskans in general. AS 45.50.471(b)(11).

16. Defendant used and employed deception, fraud, and misrepresentation to further the sales of Vioxx. Defendant knowingly concealed, suppressed, and omitted one or more material facts with the intent that others rely on the concealment, suppression, and omission in connection with the sale and advertisement of Vioxx. AS 45.50.471(b)(12).

17. Defendant knowingly or intentionally concealed or failed to disclose evidence that revealed the truth concerning the significant increased risk of heart attack and other cardiovascular problems caused by Vioxx. In addition, Defendant knowingly or intentionally set out on a course of concealing this evidence by misrepresenting the data in published literature and in advertising campaigns, and by threatening and attempting to coerce those who chose to criticize Defendant, to warn the public and the health care community, and to tell the truth about the significant risks posed by Vioxx. This conduct violates the Unfair Trade Practices and Consumer Protection Act.

18. Defendant knowingly or intentionally made, caused to be made, induced, or sought to induce the making of false statements or misrepresentations of material fact concerning the safety, or lack thereof, of Vioxx, which is information required to be provided by state law, rule, regulation, and/or provider agreement to the Alaska Medicaid Program. This conduct violates the Unfair Trade Practices and Consumer Protection Act.

19. Defendant knowingly and intentionally made claims under the Alaska Medicaid Program for a product that is substantially inadequate or inappropriate when compared to

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generally recognized standards within the health care industry or for a product that is otherwise inappropriate. This conduct violates the Unfair Trade Practices and Consumer Protection Act.

20. Defendant's knowing or intentional acts and omissions constitute repeated violations of the Alaskan statutory laws. Defendant has now admitted that Vioxx is unsafe and has taken it off the market.

CAUSATION OF DAMAGES

21. Defendant's unlawful acts and practices induced a great many Alaskans to purchase Vioxx.

22. Defendant's unlawful acts and practices induced the State of Alaska to authorize expenditure of Medicaid funds for the purchase of Vioxx.

23. Defendant's unlawful acts and practices resulted in the expenditure of millions of dollars of state funds or state controlled funds on Vioxx.

24. Defendant's unlawful acts and practices were a cause-in-fact, producing cause, and proximate cause of the purchase and expenditures described in paragraphs 21 thru 23 and have necessitated this action.

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COMPLAINT

State of Alaska v. Merck & Co., Inc., 3AN-_____CI

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PRAYER FOR RELIEF

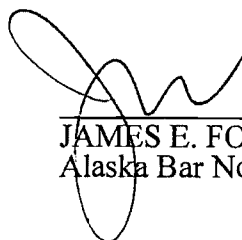
WHEREFORE, the State of Alaska demands judgment as follows:

1. For money damages in an amount that far exceeds the \$100,000 minimum jurisdictional limit of this court;
2. For restitution damages for the value of all payments that the State of Alaska made for Vioxx prescriptions;
3. For treble damages;
4. For civil penalties of \$5,000 for each separate violation of the Unfair Trade Practices and Consumer Protection Act;
5. For punitive damages;
6. For costs and attorneys' fees;
7. For prejudgment interest;
8. For post judgment interest;
9. For all other relief deemed just and equitable by the Court.

DATED: December 23, 2005.

Respectfully submitted,

FOSLER LAW GROUP, INC.



JAMES E. FOSLER
Alaska Bar No.: 9711055

COMPLAINT

State of Alaska v. Merck & Co., Inc., 3AN-_____CI

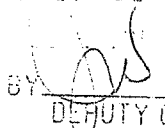
Page 8 of 8

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Attorneys for Plaintiff

FILED
STATE OF ALASKA
05-07-08 PM 12:42
BY 
DEPUTY CLERK

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,)	
)	
)	Plaintiff,
)	
vs.)	
)	
MERCK & CO., INC.,)	
)	
)	Defendant.
)	Case No: 3AN-05-

JURY DEMAND

The State of Alaska, by and through counsel, pursuant to Alaska Civil Rule 38,
demands a trial by jury.

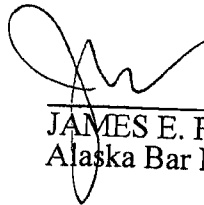
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DATED: December 23, 2005.

Respectfully submitted,

FOSLER LAW GROUP, INC.



JAMES E. FOSLER
Alaska Bar No.: 9711055

JURY DEMAND

State of Alaska v. Merck & Co., Inc., 3AN-_____ CI

Page 2 of 2

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Exhibit F

FILED IN DENVER
DISTRICT COURT
DENVER COLORADO

District Court, County of Denver, Colorado 1437 Bannock Street Denver, Colorado 80202	2006 SEP 29 AM 8:33
Plaintiff: JAMES FRANKLIN on behalf of the STATE OF COLORADO Defendant: MERCK & CO, INC.	
KRITZER/ZONIES LLC Joseph J. Zonies, Esq. #29539 Stuart A. Kritzer, Esq. #5807 140 East 19th Avenue Third Floor Denver, CO 80203 Telephone: (303) 393-1111 Facsimile: (303) 394-2917 E-mail: joe@kritzerzonies.com stuart@kritzerzonies.com CHAMBERS DANSKY & MULVAHILL LLC 1601 Blake Street, Suite 500 Denver, Colorado 80202 Telephone: (303) 825-2222 Facsimile: (303) 825-4010 Email: ddansky@ccdzwlaw.com ATTORNEYS FOR PLAINTIFF	<p>▲ COURT USE ONLY ▲</p> <p>Case Number: 06CV10485 Div.: /</p>
<p align="center">COMPLAINT AND JURY DEMAND</p>	

COMES NOW Plaintiff, James Franklin, by and through his counsel, Kritzer/Zonies, LLC, and for his Complaint against Defendant, Merck & Co., Inc., states as follows:

I. PARTIES

1. Plaintiff, James Franklin is a resident of 2466 South Gibraltar, County of Arapahoe, Colorado who is a taxpayer in and of the State of Colorado.
2. Defendant, Merck & Co., Inc., is a New Jersey corporation with its principal place of business at One Merck Drive, White House Station, New Jersey 08889. Plaintiff intends to sue that group or association doing business as "Merck", who manufactured, promoted, sold and

Delay Reduction Case

06CV10485-1

TAB

distributed the drug Vioxx to pharmacies and physicians worldwide and in the United States, and specifically in Colorado. Plaintiff intends to sue the private corporation, individual unincorporated association and/or partnerships doing business under the name of "Merck," which manufactured, sold, and was responsible for the marketing of Vioxx in the United States. Plaintiff reserves the right, if needed, to add or amend any formal names to properly reflect the correct party. At all times relevant hereto, Merck was registered to do and was doing business in the State of Colorado.

II. JURISDICTION AND VENUE

3. Plaintiff incorporates all of the allegations contained above as if fully set forth herein.

4. Plaintiff is a citizen of the State of Colorado and pays taxes to the State of Colorado for among other things the funding of Medicaid. Plaintiff brings this action derivatively on behalf of the State of Colorado and the Department of Health Care Policy and Financing (hereinafter "State of Colorado"). Plaintiff seeks in this action reimbursement of the monies paid by the State of Colorado through its Medicaid program for the prescription drug Vioxx. The State of Colorado has a legal duty to recover Medicaid funds that were expended as a result of the wrongful acts of a third party, including fraud. Plaintiff, through counsel, has requested that the State of Colorado act to recover these funds and Colorado has failed to act in a timely manner.

5. Defendant Merck transacted business in Colorado by, among other things, advertising, soliciting, selling, and distributing the pharmaceutical product known as Vioxx to purchasers in Colorado. This Court has jurisdiction over this matter.

6. As derivative plaintiff, State of Colorado, is not a citizen for purposes of diversity jurisdiction, no federal court can exercise subject matter jurisdiction over this case by virtue of diversity of citizenship.

7. Pursuant to C.R.C.P. 98 venue is proper because some of Defendant's unlawful acts and practices that give rise to this Complaint arose in this district and Defendant was and is doing business here.

III. BACKGROUND INFORMATION

8. Plaintiff incorporates all of the allegations contained above as if fully set forth herein.

9. Vioxx is the brand name of Rofecoxib, one of a class of drugs called prostaglandins, which drugs work to reduce inflammation and pain by providing analgesic and anti-inflammatory benefits to persons with, among other conditions, arthritis and muscle or joint pain. Prostaglandins are COX (cyclooxygenase) inhibitors. COX enzymes metabolize arachidonic acid to produce prostaglandins.

10. Vioxx is a COX-2 inhibitor, which is designed to produce prostaglandins at inflammatory sites and to produce prostacyclin, a vasodilator and an inhibitor of platelet aggregation.

11. Merck submitted an Application to Market a New Drug for Human Use ("NDA") for rofecoxib to the United States Food & Drug Administration (hereinafter referred to as the "FDA") on November 23, 1998, for tablets at doses of 12.5 mg. and 25 mg., for relief of the signs and symptoms of osteoarthritis, the management of acute pain, and the treatment of primary dysmenorrhea. This application was denoted NDA 21-042 by the FDA.

10. Merck also submitted an NDA for rofecoxib to the FDA on November 23, 1998, for oral suspension at doses of 12.5 mg./ml and 25 mg/ml for relief of the signs and symptoms of osteoarthritis, the management of acute pain and the treatment of primary dysmenorrhea. This application was denoted NDA 21-052 by the FDA.

11. On or about May 20, 1999, the FDA approved NDA 21-042 and NDA 21-052 for rofecoxib (Vioxx) for the relief of the signs and symptoms of osteoarthritis, the management of acute pain and the treatment of primary dysmenorrhea.

12. Defendant requested and successfully marketed Vioxx to be placed on the State of Colorado Medicaid Program's list of drugs subject to reimbursement. In making this request, the Defendant represented that Vioxx was at least as safe as other drugs of a similar class and/or type used for the same purposes.

13. At the time the drug was approved by the FDA, the labeling for rofecoxib stated, in the section entitled "Special Studies - Upper Endoscopy in Patients with Osteoarthritis," "Treatment with Vioxx 25 mg daily or 50 mg daily was associated with a significantly lower percentage of patients with endoscopic gastroduodenal ulcers than treatment with ibuprofen 2400 mg daily. However, the studies cannot rule out at least some increase in the rate of endoscopic gastroduodenal ulcers when comparing Vioxx to placebo." The "Warnings" section of the labeling for rofecoxib, at the time the drug was approved by the FDA, contains a section, "Gastrointestinal (GI) Effects—Risk of GI Ulceration, Bleeding, and Perforation."

14. Defendant Merck submitted NDA-007 with the goal of establishing a gastrointestinal ("GI") safety claim for rofecoxib. In conjunction with the NDA, Defendant Merck performed the Vioxx GI Outcomes Research (VIGOR) Protocol, No. 088-04, entitled "A Double-Blind, Randomized, Stratified, Parallel-Group Study to Assess the Incidence of PUBs During Chronic Treatment with MK-0966 or Naproxen in Patients With Rheumatoid Arthritis: U.S. Cohort." The VIGOR study was performed from January 6, 1999 through March 17, 2000.

15. The objectives of the VIGOR study were to (1) "determine the relative risk of confirmed PUB (Perforation, Ulcers, Bleeding) in patients taking MK-0966 50 mg daily compared to patients in the group taking naproxen 1000 mg/day", and (2) "study the safety and tolerability of MK-0966 in patients with rheumatoid arthritis."

16. In March of 2000, the VIGOR study found Vioxx patients had double the rate of serious cardiovascular problems than those on Naproxen, an older non-steroidal anti-inflammatory drug (NSAID). The VIGOR data revealed that (a) patients on Vioxx were five times more likely to suffer a heart attack as compared to patients on Naproxen; and (b) patients on Vioxx were 2.3 times more likely to suffer serious cardiovascular disease (including heart attacks, ischemic stroke, unstable angina, and sudden unexplained death) as compared to patients on Naproxen.

17. On March 27, 2000, Merck issued a press release leading off with the finding that Vioxx caused fewer digestive tract problems than Naproxen. Merck continued to assert that it was not that Vioxx caused cardiovascular problems, but that Naproxen protected against them.

18. In June 2000, in industry-sponsored studies presented to the European United League Against Rheumatism (EULAR), an organization of which Merck is a corporate sponsor, it was shown that Vioxx use resulted in a statistically significant increase in hypertension and myocardial infarction and stroke.

19. Not only did Merck do nothing to further accurately publish these studies or warn consumers or the State of Colorado but, in August 2000, it denied the results with respect to hypertension in the official publication of the American Pharmaceutical Association, *Pharmacy Today*.

20. From March 2000-September 2004, Merck continued to deny the ill health effects associated with Vioxx while at the same time reaping profits obtained through its non-disclosure and concealment. Merck engaged in a massive advertising and sampling program and gained continued increases in the market share, which enhanced Merck's financial stability to the detriment of its consumers and the State of Colorado. As a result of Merck's scheme, it reaped more than \$2 billion in profit in the year 2000 alone, and appropriated approximately 23 percent share of the market.

21. Merck continued to profit from their scheme, concert of action and/or conspiracy by withholding information from the State of Colorado, the consuming public, and the health care industry.

22. In November of 2000, *The New England Journal of Medicine* published the VIGOR study (VIGOR = Vioxx Gastrointestinal Outcomes Research) and Merck responded by knowingly downplaying and/or withholding the severity of cardiovascular risks associated with Vioxx consumption over Naproxen consumption.

23. Further, in its January 23, 2001 8-K filing with the Securities and Exchange Commission, Defendant failed to mention the cardiac and cardi thrombotic findings of the VIGOR study:

"Our results reflect the strength of our growth strategy," Mr. Gilmartin said. "Our five key products, VIOXX, ZOCOR, COZAAR/HYZAAR*, FOSAMAX and SINGULAIR, drove Merck's performance for the year and created a powerful

platform for growth". These products accounted for 57% of Merck's worldwide human health sales for 2000 and 61% for the fourth quarter.

"Each of the five medicines offers unique competitive advantages," Mr. Gilmartin said. VIOXX, a once-a-day medicine, is the only COX-2 indicated in the United States both for osteoarthritis and acute pain. Since its extraordinarily successful 1999 launch, VIOXX has become the world's fastest growing branded prescription arthritis medicine, and it is already Merck's second largest-selling medicine. In the United States, VIOXX now accounts for approximately 50 percent of new prescriptions in the COX-2 class, despite being second to market in this class in the United States, VIOXX achieved \$2.2 billion in sales for the full year 2000, with \$700 million in the fourth quarter.

A Food and Drug Administration (FDA) Advisory Committee meeting is scheduled for February 8 to review labeling changes Merck has requested based on the strong results of the VIGOR Study. This 8,000-patient gastrointestinal outcomes research study, in which VIOXX reduced the risk of serious gastrointestinal complications by half compared to the NSAID naproxen, was published in November in *The New England Journal Of Medicine*. Another study, presented in November, showed that VIOXX significantly reduced moderate-to-severe acute pain after dental surgery to a greater degree compared to codeine combined with acetaminophen.

24. In February 2001, an FDA Advisory Panel recommended the FDA require a label change warning of the possible link to cardiovascular problems.

25. In documents dated February 8, 2001, according to the FDA Advisory Committee briefing document in the VIGOR Study, the potential advantage of decreasing the risk of complicated gastrointestinal side effects was paralleled by the increased risk of developing cardiovascular thrombotic events.

26. On May 22, 2001 Merck issued a press release through the *PR Newswire* that stated, "In response to news and analyst reports of data the Company first released a year ago, Merck & Co., Inc. today reconfirmed the favorable cardiovascular safety profile of Vioxx".

27. On August 22, 2001, Dr. Eric Topol and Dr. Steven Nessen's article, "Risk of Cardiovascular Events Associates With Selective Cox-2 Inhibitors," was published in the *Journal of the American Medical Association (JAMA)* and reported the findings of the Cleveland Clinic's study that "current data would suggest that the use of these so-called "COX-2 inhibitors" might lead to increased cardiovascular events."

28. On August 21, 2001, the day before the *JAMA* article was published, Merck commented in a published report in *Bloomberg News* that "We have additional data beyond what they [Topol and Nessen] cite, and the findings are very, very reassuring. Vioxx does not result in any increase in cardiovascular events compared to placebo."

29. On August 23, 2001 Merck stated in a press release that "the Company stands behind the overall and cardiovascular safety profile ...of Vioxx."

30. On September 17, 2001, Thomas W. Abrams, Director of the FDA Division of Drug Marketing, Advertising and Communications issued a "Warning Letter" to Raymond Gilmartin, President and CEO of Merck.

31. The Warning Letter stated that Defendant Merck had "engaged in a promotional campaign for Vioxx that minimizes the potentially serious cardiovascular findings that were observed in the Vioxx Gastrointestinal Outcomes Research (VIGOR) study, and thus, misrepresents the safety profile for Vioxx." The letter further states:

Specifically, your promotional campaign discounts the fact that in the VIGOR study, patients on Vioxx were observed to have a four to five fold increase in myocardial infarctions (MIs) compared to patients on the comparator non-steroidal anti-inflammatory drug (NSAID), Naprosyn (naproxen).

32. The eight page Warning Letter outlines, in detail, the conduct of Defendant Merck that supports the FDA's issuance of the Warning Letter, and makes the following "Conclusions and Requested Actions":

The promotional activities and materials described above minimize the potentially serious Cardiovascular findings that were observed in the VIGOR study, minimize the Vioxx/Coumadin drug interaction, omit crucial risk information associated with Vioxx therapy, contain unsubstantiated comparative claims, and promote unapproved uses. On December 16, 1999, we also objected to your dissemination of promotional materials for Vioxx that misrepresented Vioxx's safety profile, contained unsubstantiated comparative claims, and lacked fair balance.

Due to the seriousness of these violations, and the fact that your violative promotion of Vioxx has continued despite our prior written notification regarding similar violations, we request that you provide a detailed response to the issues raised in this Warning Letter on or before October 1, 2001.

This response should contain an action plan that includes a comprehensive plan to disseminate corrective messages about the issues discussed in this letter or the audiences that received these misleading messages. This corrective action plan should also include:

1. Immediately ceasing all violative promotional activities, and the dissemination of violative promotional materials for Vioxx.
2. Issuing a "Dear Healthcare Provider" letter to correct false or misleading impressions and information. This proposed letter should be submitted to us for review prior to its release. After agreement is reached

on the content and audience, the letter should be disseminated by direct mail to all healthcare providers who were, or may have been exposed to the violative promotion.

3. A written statement of your intent to comply with "1" and "2" above.

33. Merck was also aware at this time of the increased risks of thrombotic (blood clotting) adverse effects such as strokes and blood clots in the legs, hypertension, and altered kidney function. However, Vioxx was by then a blockbuster moneymaker and Merck decided to protect its "cash cow" at all costs through the continued false and misleading claims to the State of Colorado, the general public (including Medicaid recipients) and treating physicians of the general public (including Medicaid recipients), through direct to consumer advertising and through its agents, servants and employees.

34. On January 12, 2002, Dr. Wayne A. Ray, a Professor of Preventive Medicine at Vanderbilt University, and others, reported in an article published in *The Lancet* that Naproxen did not have significant protective cardiovascular effect and that Vioxx, when taken at higher doses that had become common, of which Merck had become aware and anticipated, posed an increased risk of heart-related problems.

35. In 2002, Merck was spending more than \$100 million a year in direct-to-consumer advertising. Such advertising was used by Merck to portray Vioxx as safe, which clearly underestimated the risks of cardiovascular events. In addition, Merck continued to aggressively promote Vioxx to the medical community and the State of Colorado by encouraging its sales representatives to deliver large quantities of free samples to the medical community, including the treating doctors of citizens of the State of Colorado (particularly Medicaid recipients).

36. In 2002 and 2003, Merck refused requests from the American Heart Association, the National Stroke Association and the Arthritis Foundation that it conduct additional safety studies, while continuing to claim that Vioxx was safe and that it did not plan to conduct any such study.

37. On October 30, 2003, an article in *The Wall Street Journal* reported that another study sponsored by Merck and presented at the annual meeting of the American College of Rheumatology confirmed an increased risk of heart attacks in patients taking Vioxx. According to *The Wall Street Journal*, within the first 30 days of taking Vioxx the risk of a heart attack was increased by 30% as compared to Celebrex. This study looked at the records of 54,475 Medicare patients, all of whom were over 65, and was described by Dr. Eric Topol as "the best study to date".

38. In 2003, Dr. Jerry Avorn, a Divisional Director at Brigham and Women's Hospital in Boston, and his colleague Dr. Daniel H. Solomon reported on a Merck financed study based on a survey of patient records that found Vioxx, even at some moderate dosages, increased cardiovascular risk.

39. Merck disputed the findings of the Avorn-Solomon study, and the name of the Company epidemiologist who had worked on it was removed from the report before it was published in a medical journal.

40. In 2003, worldwide sales of Vioxx totaled \$2.5 billion.

41. To further increase the appeal of Vioxx to the general public through Merck's direct to consumer advertising, from 1999 through 2004, it used Olympic gold medalists Dorothy Hamill and Bruce Jenner to promote it.

42. From January through June 2004, Merck spent an estimated \$45 million in advertising Vioxx.

43. In May 2004, the results of a study funded by the Canadian government were published in *The Lancet*. The study reviewed data from 1.3 million elderly patients (66 and older) taking Vioxx vs. Celebrex vs. a common arthritis pain pill (NSAID) vs. no medication. The records from approximately 130,000 persons randomly reviewed from the population base found that persons taking Vioxx had an 80% increase in hospital admissions for congestive heart failure within one year of taking Vioxx when compared to persons taking NSAIDS.

44. On August 25, 2004, Dr. David Graham, Associate Director for Science in the FDA's Office of Drug Safety, presented results of a database analysis of 1.4 million patients that showed Vioxx users are more likely to suffer a heart attack or sudden cardiac death than those taking Celebrex or an older NSAID.

45. Despite the foregoing, on August 26, 2004, Merck continued to represent to consumers and the State of Colorado that Vioxx was safe, and that any cardiovascular and/or cardiothrombotic side effects were not associated with the drug. Merck stated in a press release that "Merck stands behind the efficacy, overall safety and cardiovascular safety of Vioxx".

46. On September 30, 2004, Merck finally withdrew Vioxx from the United States and more than 80 other countries, after obtaining additional information from its own studies which had been instigated by Merck to determine if it could claim Vioxx protects against the recurrence of colon polyps, which can become cancerous, that the group in the study taking Vioxx after 18 months had twice as high a risk of developing cardiovascular disease as the placebo group.

47. Up to and including September 30, 2004, Defendant Merck continued to represent to consumers and the State of Colorado that Vioxx was safe, and that any cardiovascular and/or cardiothrombotic side effects were not associated with the drug. The defendant downplayed any potential gastrointestinal side effects of Vioxx, promoting it as safer and more efficacious than other medications approved for treatment of similar conditions.

FIRST CLAIM FOR RELIEF – FRAUD AND NONDISCLOSURE

48. Plaintiff hereby incorporates the above paragraphs as though set forth fully herein.

49. Defendant committed actual fraud by making material representations, which were false, knowing that such material representations were false and/or with reckless disregard for the truth or falsity of the material representations, with the intent that the State of Colorado would rely on such material representations when listing the drug as approved for payment/reimbursement and in paying for the drug. State of Colorado acted in actual and justifiable reliance on such material misrepresentations and was injured as a result by making payments for the drug.

50. In addition, and in the alternative if necessary, Defendant knowingly omitted material information, which omission constitutes a positive misrepresentation of material fact, with the intent that the State of Colorado would rely on Defendant's misrepresentations. The State of Colorado acted in actual and justifiable reliance on Defendant's misrepresentations and was injured as a result by making payments for the drug.

51. Defendant committed constructive fraud by breaching one or more legal or equitable duties owed to Plaintiff relating to the Vioxx at issue in this lawsuit. Said breach or breaches constitute fraud because of their propensity to deceive others or constitute an injury to public interest or public policy.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in favor of Plaintiff and for the State of Colorado for disgorgement to the State of Colorado of millions of dollars of state controlled funds used to purchase Vioxx through the Medicaid program and for attorneys fees, interest and costs and such other and further relief as the Court deems just and proper.

PLAINTIFF RESPECTFULLY DEMANDS A TRIAL BY JURY.

Respectfully submitted September 29, 2006.

KRITZER/ZONIES LLC

By: /s/ Joseph J. Zonies

Joseph J. Zonies, #29539

Stuart A. Kritzer, #5807

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Denver, CO 80203

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Telephone: (303) 825-2222

Facsimile: (303) 825-4010

Email: ddansky@ccdzwlaw.com

ATTORNEYS FOR PLAINTIFF

Exhibit G

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

----- X
THE PEOPLE OF THE STATE OF NEW YORK, :
by ANDREW M. CUOMO, Attorney General of :
the State of New York, and THE CITY OF NEW :
YORK, :
:

Plaintiffs, :

- against - :

MERCK & CO., INC., :

Defendant. :
----- X



COMPLAINT

Index No. 07/406439

TO: THE SUPREME COURT OF THE STATE OF NEW YORK

The People of the State of New York, by their attorney, Andrew M. Cuomo, Attorney General of the State of New York, and The City of New York, by its attorney, Michael A. Cardozo, Corporation Counsel of the City of New York, allege the following upon information and belief:

PRELIMINARY STATEMENT

1. Merck & Co., Inc. ("Merck") is a pharmaceutical manufacturer with pharmaceutical sales of billions of dollars each year. Merck has engaged in repeated and persistent fraud and has caused false and fraudulent claims to be submitted to the New York State Medical Assistance Program ("Medicaid") and the Elderly Pharmaceutical Insurance Coverage ("EPIC") program by suppressing, misrepresenting and concealing material information in its communications with doctors and patients concerning the seriousness of the cardiovascular risks associated with Merck's drug Vioxx (rofecoxib).

2. Merck began to market Vioxx in 1999. Vioxx is a non-steroidal anti-inflammatory drug ("NSAID") of a type known as COX-2 inhibitors. It was initially approved to treat the symptoms of osteoarthritis, acute pain in adults, and dysmenorrhea (painful menstruation), and was eventually indicated for rheumatoid arthritis, migraine headaches, and juvenile rheumatoid arthritis. Between 1999 and 2003, over 90 million prescriptions for Vioxx were dispensed in the United States.

3. New York Medicaid and EPIC have paid over \$100 million for Vioxx since it entered the market in 1999. Tens of millions of these dollars were paid for Vioxx prescriptions and refills for patients with pre-existing cardiovascular risk factors.

4. Between 2001 and 2004, New York consumers spent millions of dollars on Vioxx.

5. Merck withdrew Vioxx from the market in September 2004 because of its excessive cardiovascular risks, including the increased risk of heart attack and stroke. Merck stated that it had concluded that the withdrawal was "the responsible course to take."

6. Before removing Vioxx from the market, Merck undertook a concerted and tenacious campaign of false and fraudulent statements to minimize the import and seriousness of any reports about the possible association between Vioxx and serious cardiovascular events, especially myocardial infarction ("heart attacks").

7. Merck tried to distort each negative disclosure about Vioxx. Its responses, aimed at doctors and consumers, misrepresented the true picture of the danger to patients who took Vioxx, especially the danger posed to patients with established coronary artery disease. Merck cherry-picked the outcomes from its own research, omitting material information that would have communicated Vioxx's real cardiovascular dangers.

8. As a result of Merck's disinformation campaign, which continued until just one month before Merck withdrew Vioxx from the market, New York physicians wrote and continued to write prescriptions for Vioxx that they otherwise would not have written, specifically for patients with established coronary artery disease. Absent Merck's disinformation campaign, those consumers would not have purchased and taken Vioxx, and third-party payors, including Medicaid, would not have paid for Vioxx.

9. The Attorney General of the State of New York and the City of New York bring this action to prevent Merck from engaging in similar fraudulent and deceptive conduct in the future and to obtain damages and restitution for the consumers and government agencies defrauded by Merck, as well as penalties and costs.

JURISDICTION AND PARTIES

10. Andrew M. Cuomo is the Attorney General of the State of New York. He is authorized to institute all actions and proceedings in which the State is interested, N.Y. Executive Law § 63(1); to seek an order that enjoins repeated or persistent fraudulent or illegal business acts or practices and awards damages and restitution for such acts, N.Y. Executive Law § 63(12); to recover treble damages for overpayments of public funds obtained by means of false statements or other fraudulent schemes, N.Y. Social Services Law § 145-b(2); and to recover three times the amount of damages sustained by the state on account of Merck's false statements along with civil penalties of between \$6,000 and \$12,000 per violation pursuant to the New York False Claims Act, N.Y. Finance Law §§ 189, 190(1).